



Role of Prerequisite Programs in Extraneous Material Management

**William H. Sveum Ph.D.
Associate Director of Regulatory Affairs
Kraft Foods North America**



Prerequisite Programs

- **Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food**
- **Prerequisite programs include GMP's, equipment and process flow design, sanitation, maintenance, receiving and storage, and personnel training**
- **Prerequisite programs must be developed, implemented, and documented before conducting the hazard analysis and implementing a HACCP plan**

Foundation of Food Safety Management: Prerequisite Programs

General Quality Systems;
Monitoring Programs; GMP
Use of Approved Suppliers
Rework Practices
Formulation (e.g., excess restricted
ingredient addition)
Post Cook Recontamination
Product Sequencing
Extraneous Detection / Removal
Programs
Brine Programs (treatment & testing)

Recalls
Hold & Release
Recall Procedures
Traceability / Code Dating

Specifications
Raw Materials Packaging
Formulas Labeling
Manufacturing Procedures
Finished Product

Premises
Building Structure & Utility Systems
Outside Property
Water Quality Program
(treatment & testing)

Receiving / Storage
Raw Material Management
Receiving / Storage Distribution
Certificate of Analysis (COA)
Letters of Guarantee
Hold & Release
Truck / Carrier Inspection
Label Review for Accuracy (e.g., "keep
refrigerated", cooking instructions)

Equipment Performance & Maintenance
Preventative Maintenance
Equipment Calibration
Compressed Air Filtration
Equipment Design

Sanitation
Pest Control
Equipment Cleaning
Housekeeping
Period Cleaning

Personnel Training Program
Employee Hygiene
Employee Practices



Prerequisite Programs

The manufacture of safe food requires the use of a HACCP system built on a foundation of well-designed and administered prerequisite programs

- **NACMCF**
- **Codex**
- **CFIA**
- **USDA Generic Model**

Industry Petition to Amend FSIS HACCP Regulations

- **National Food Processors Association comments suggested that the degree of risk presented to consumers by the potential hazard dictate the control**

NFPA proposed:

- **[I]f violation of a control limit clearly represents an inappropriate food safety risk that should lead to action against product, then inclusion of the potential hazard within a HACCP program is generally warranted. However, if non-conformance with a control limit is undesirable, but unlikely to have health implications and therefore unlikely to require action against product, then ... inclusion of such a potential hazard in a HACCP plan is not generally appropriate.... (Comments to Docket No. 00-014R2, filed December 21, 2000 by the National Food Processors Association, page 4).**



Food Safety System Definitions

- **Critical Control Point:** (CFR417.1) “A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.”
- **Prerequisite Programs:** Represent the sum of programs, practices and procedures which must be applied to design, produce and distribute safe products in a clean, sanitary environment.



Benefits of Prerequisite Programs

- **Focuses food safety management on process control**
- **Doesn't rely on the limited effectiveness of after the fact inspection practices**
- **Directs resources to effectively manage scientifically based CCP's**
- **Effective implementation of HACCP requires a sound foundation of PP's capable of reducing or even eliminating the likelihood that a potential food safety hazard will occur in a process**



Food Safety Systems

- **Control all potential food safety hazards**
- **Food safety hazards that are “reasonably likely to occur” must be controlled by a CCP**
- **Some hazards are not “food safety hazards reasonably likely to occur” because PP’s are in place**
- **Use validated CCP’s supported by developed, implemented, and documented PP’s**
- **PP’s must be audited for effectiveness**
- **Prerequisite program records associated with the HACCP plan are accessible for review**



How Kraft Conducts a Hazard Analysis

- **Identify every potential food safety hazard for all ingredients, packaging materials, and processing steps**
- **Determine potential frequency and severity**
- **Prerequisite programs generate information that supports the hazard analysis**
- **Use Prerequisite Programs whenever a hazard can be reduced or eliminated through a series of basic control programs**
 - **GMP's+ Equipment Checks+Raw Material Inspection+Routine Sanitation+ Metal Detection**
- **Focus CCP's on critical food safety hazards in a process**



Hazard Analysis Is Specific for Each Process

- Extraneous material may be a hazard “reasonably likely to occur” depending on the process
- Lack of sufficient ingredient history to support decision process
- Packaging material may introduce a risk-glass



Hazard Analysis - Extraneous Material

Rationale for classifying extraneous material as a hazard “not reasonably likely to occur”

- **Ingredient history**
- **Process history indicates introduction of foreign material large enough to cause injury is not likely to occur at specific steps**
- **Effectiveness of GMP's and PP's minimizing the likelihood of occurrence**
- **Scientific references**



Review of Hazard Analysis

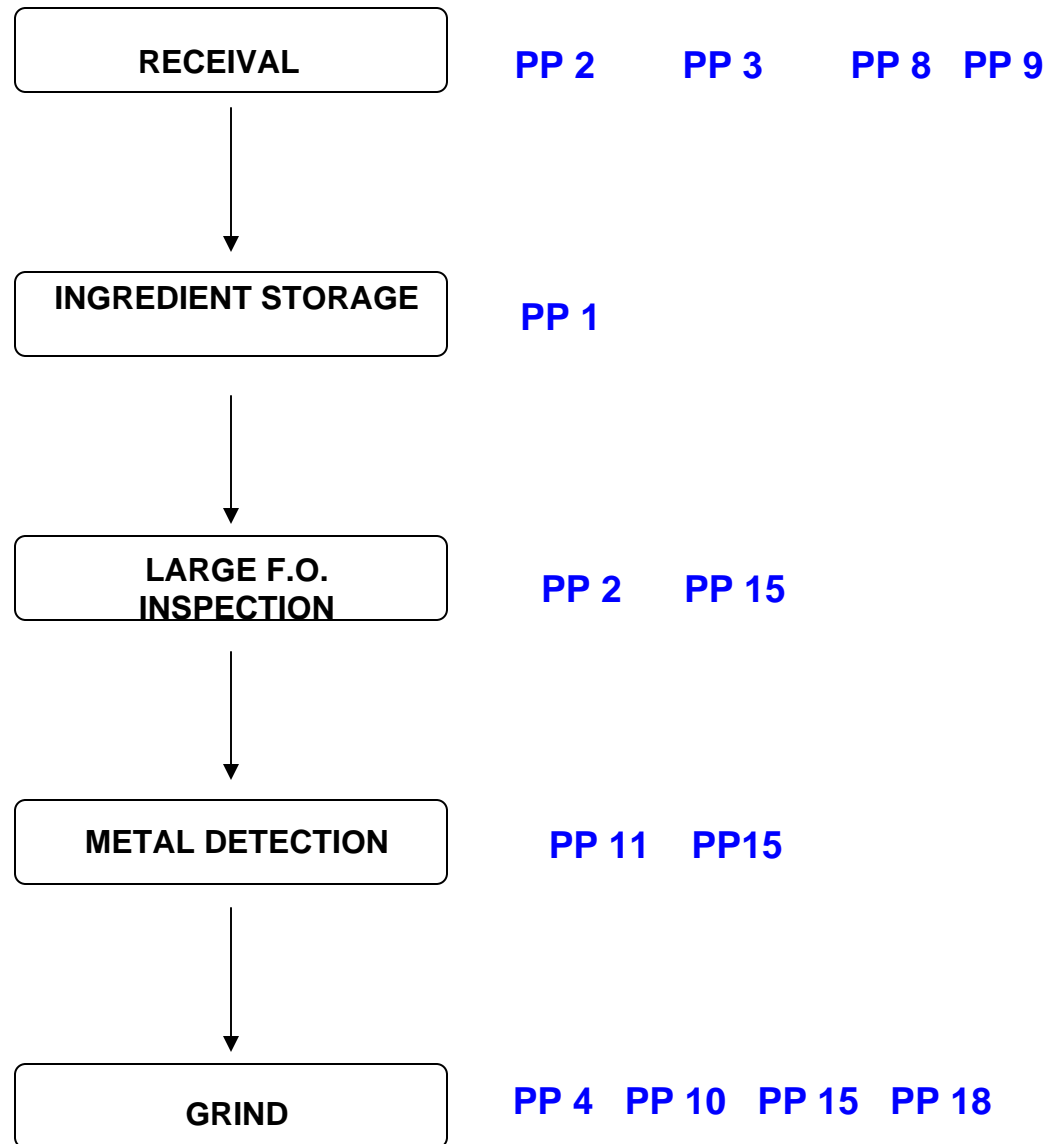
- **Identify all potential hazards that pose a food safety risk**
- **Utilize a series of prerequisite programs to reduce or eliminate the risks these hazards might create**
- **HACCP Plans:**
 - **Use an integrated approach to food safety management**
 - **Select CCP's based on science**
 - **Support CCP's with Prerequisite Programs**
 - **Focus attention and resources on critical HACCP activities**



Processes to Control & Eliminate Extraneous Material in Comminuted Cooked Sausage

- Meat Receival
- Meat Inspection
- Grinding
- Rework Handling
- Batching
- Corn Syrup Filter
- Pump Rotors
- Metal Detector
- Emulsification
- Rare Earth Magnet
- Finished Product Metal Detector
- Visual Inspection
- Clean up

HACCP PROCESS FLOW EXTRANEEOUS MATERIAL





Meat Inspection

- **Large foreign object inspection by running meat over an inspection belt prior to grinding**
- **All trimmings are run through a metal detector set to detect 10.5 mm ferrous/10.0 mm non-ferrous**
- **In line metal detector checked for proper function daily**
- **Plant Policy : Plant Manager's Standard Instructions**
- **Document : Foreign Objects In Raw Materials report, metal detector verification, grinding log**



Grinding

- **Disassemble grinders after each lot, vendor or species change**
- **Grinder is inspected for damage or extraneous material behind the plate. Grinder also inspected anytime disassembled and during clean up**
- **Grinder plates and knives changed daily and removed from service at signs of excessive wear**
- **Plant Policy : Plant Manager's Standard Instruction**
- **Document : grinding log, pre-op sheet**



Finished Product Metal Detector

- In line metal detector checked for proper function at start-up, every 2 hours, & end-of-run
- All finished product is run through a metal detector set to detect 2.5 mm stainless steel
- Plant Policy : Plant Manager's Standard Instruction
- Document : metal detector check sheet



Key Takeaways

- **Kraft Food's approach to HACCP Management**
 - **Use an integrated approach to food safety management**
 - **Use science to select CCP's**
 - **Failure to recognize Prerequisite Programs diverts attention and resources from critical HACCP activities**
 - **Prerequisite Programs are used whenever a hazard can be reduced or eliminated through basic control programs**
 - **GMP's, Equipment Checks, Temperature Controls, Routine Sanitation, Metal Detection**